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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,475	11/11/2003	Vincenzo Cerundolo	NY-LUD-5629-3-DIV	8208

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EXAMINER	
DIBRINO, MARIANNE NMN	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/706,475	CERUNDOLO ET AL.	
	Examiner	Art Unit	
	DiBrino Marianne	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *49-58* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed 12/15/03 is acknowledged and has been entered.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 49-54, drawn to a method for providing proliferation of CTL comprising contacting a CTLp with a peptide/composition thereof, of formula SLLMWITQX wherein X is Ala, Val, Leu , Ile, Pro, Phe, Met, Trp or Gly, classified in Class 424, subclass 185.1 and Class 514, subclass 15 and Class 435, subclass 252.3.

II. Claims 55 and 56, drawn to a method for provoking proliferation of CTL comprising contacting a sample containing a cell that presents SLLMWITQX wherein X is any amino acid residue except Cys/HLA complexes on its surface with a CTLp, classified in Class 424, subclass 93.7 and Class 435, subclass 93.7.

III. Claim 57, drawn to a method for facilitating delivery of a tumor rejection antigen of formula SLLMWITQX wherein X is Ala, Val, Leu , Ile, Pro, Phe, Met, Trp or Gly, to an MHC molecule, said method comprising administering a fusion protein to a cell which is taken up by the cell and cleaved to form the peptide, followed by delivery of said peptide to said MHC molecule, classified in Class 424, subclass 192.1 and Class 514, subclass 2.

IV. Claims 57 and 58, drawn to a method for facilitating delivery of a tumor rejection antigen of formula SLLMWITQX wherein X is Ala, Val, Leu , Ile, Pro, Phe, Met, Trp or Gly, to an MHC molecule, said method comprising administering a nucleic acid molecule encoding a fusion protein to a cell which is taken up by the cell and cleaved to form the peptide, followed by delivery of said peptide to said MHC molecule, classified in Class 435, subclass 320.1 and Class 514, subclass 44.

3. Inventions I -IV are different methods of use.

These inventions require different ingredients and process steps to accomplish the use of provoking proliferation of CTL (Inventions I and II) or for facilitating delivery of a tumor rejection antigen (Inventions II and III). For example, the method of Invention I uses a peptide, whereas the method of Invention II uses a cell expressing HLA/peptide on the cell surface, whereas the method of Invention III uses a fusion protein, whereas the method of Invention IV uses a nucleic acid molecule encoding a fusion protein.

Therefore they are patentably distinct.

4. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-IV is not required for any other group from Groups I-IV and Groups I-IV have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

5. **If Applicant elects Group I**, Applicant is further required to (1) elect a single disclosed species (a ***specific peptide***, for example, SLLMWITQA, SEQ ID NO: 6) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added, AND to elect a method that is one of in vivo or in vitro administration of peptide.

These species are distinct because their structures are different.

6. **If Applicant elects Group II**, Applicant is further required to (1) elect a single disclosed species of cell expressing a specific HLA/peptide complex (a ***specific peptide***, for example, SLLMWITQA(SEQ ID NO: 6)/HLA-A2) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added, AND to elect a method that is one of in vivo or in vitro administration of cell that expresses HLA/peptide complex on its surface.

These species are distinct because their structures are different.

7. **If Applicant elects Group III**, Applicant is further required to (1) elect a single disclosed species (a ***fusion protein that is cleaved to form a specific peptide***, for example, SLLMWITQA, SEQ ID NO: 6) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added, AND to elect a method that is one of in vivo or in vitro administration of a fusion protein to a cell.

These species are distinct because their structures are different.

8. **If Applicant elects Group IV**, Applicant is further required to (1) elect a single disclosed species (*a nucleic acid molecule that encodes a* ***fusion protein that is cleaved to form a specific peptide***, for example, SLLMWITQA, SEQ ID NO: 6) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added, AND to elect a method that is one of in vivo or in vitro administration of a nucleic acid encoding a fusion protein to a cell.

These species are distinct because their structures are different.

9. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

10. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

11. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

12. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

13. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chan Y Christina, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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April 16, 2004

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